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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,705	12/11/2001	Scott J. Addonizio	1133279-0014	7327

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,705

Applicant(s)

ADDONIZIO ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004, 23 June 2005, 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29, 30, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/094,402.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed September 13, 2004 and responses to the notices of non-compliant amendments filed June 23, 2005 and September 9, 2005 have been entered. The changes to the abstract, specification, drawings and claims have been approved by the examiner. Claims 28 and 38-42 have been canceled. Claims 1-27 and 29-37 are currently pending, of which claims 34-37 remain withdrawn from further consideration for being drawn to a non-elected species. The claims being considered for further examination on the merits are claims 1-27 and 29-33.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/094,402 filed on June 10, 1998.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on June 23, 2005 has been considered by the examiner.

Response to Arguments

4. Applicant's arguments, see pages 21-23 of the amendment filed September 13, 2004, with respect to the rejection(s) of claim(s) 1-27, 29, 30, 32 and 33 under 35 U.S.C. 102(e) as

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being anticipated by Cottone, Jr. et al. (USPAP 2002/0116044) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kim (USPN 6,270,524) and Cottone et al. (USPN 6,432,132).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim (USPN 6,270,524).

Kim discloses an expandable stent with all the elements of claims 1 and 10. With respect to claim 1, see Figure 2C below for a stent (10) with a main body (12) including a plurality of expandable helical segments and a plurality of main body cylindrical elements (14) having collinear cylindrical axes, wherein the main body cylindrical elements (14) are adjacent to one another and are attached to one another by the helical segments. Each main body cylindrical element (14) includes a circumference that is substantially identical to that of an adjacent cylindrical element (14), and a plurality of circumferential segments joined together by portions of the helical segments form the cylindrical element (14). The plurality of circumferential segments comprises a majority of the circumference of each cylindrical element (14).

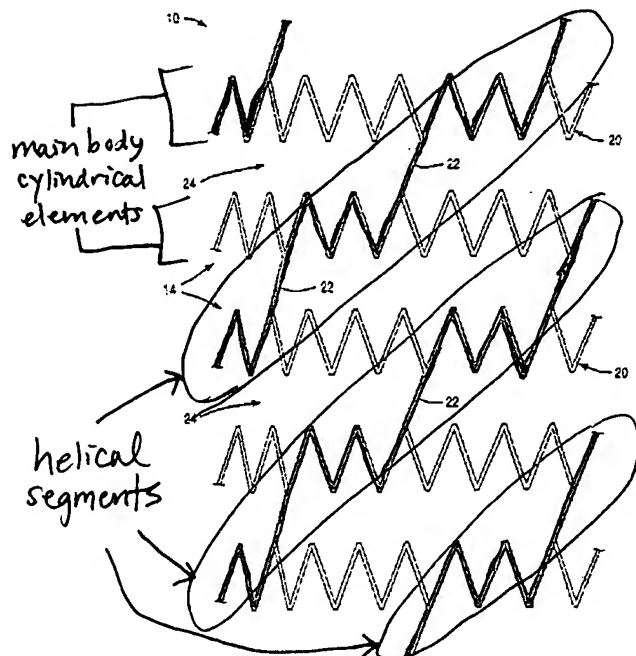


FIG. 2C

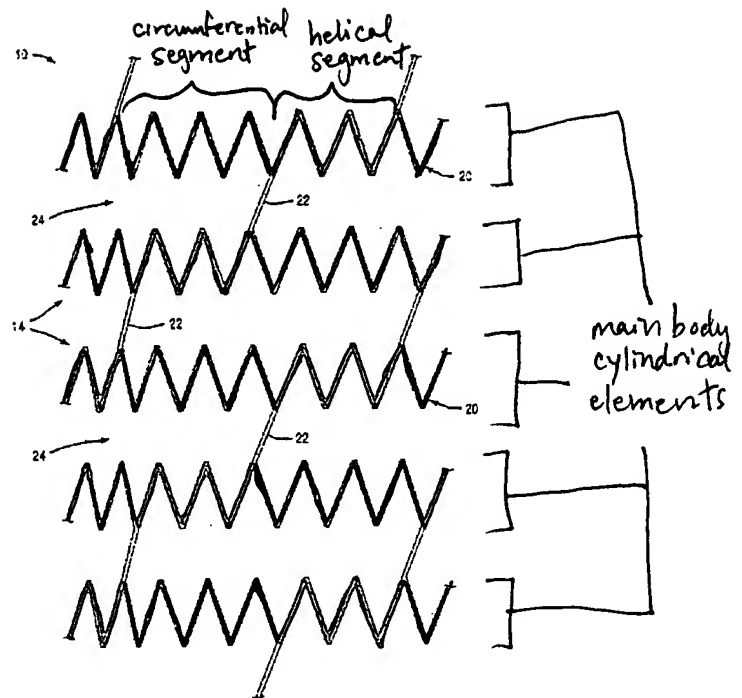


FIG. 2C

With respect to claim 10, see Figure 2A below for an expandable stent (10) including a first non-helical endzone, a second non-helical endzone, and a generally cylindrically shaped main body (12) having a cylindrical axis, being located between the first and second endzones, and including a plurality of adjacent cylindrical main body elements (14) connected together and having cylindrical axes collinear with the main body cylindrical axis. See Figure 2C below for the main body elements (14) including a plurality of first expandable circumferential segments having a circumferential dimension, and a plurality of second expandable circumferential segments having a circumferential dimension that is less than the first expandable segment circumferential dimension. Each of the second expandable segments is connected to two first expandable segments. The cylindrical main body elements (14) are joined by connecting together second expandable circumferential segments of adjacent cylindrical main body

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elements (14) in helical patterns, thereby forming a plurality of generally parallel helices in the main body (12).

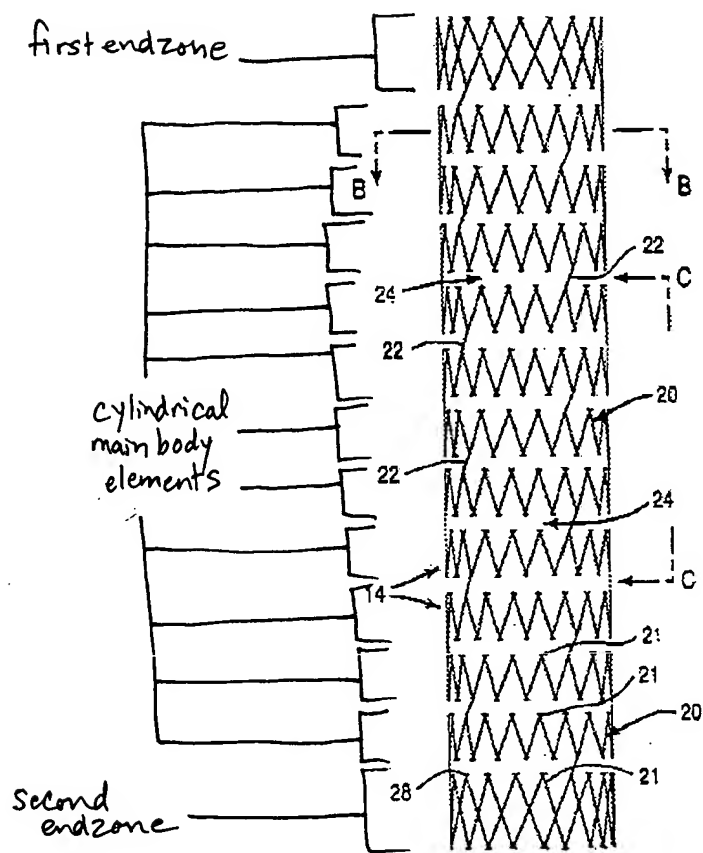


FIG. 2A

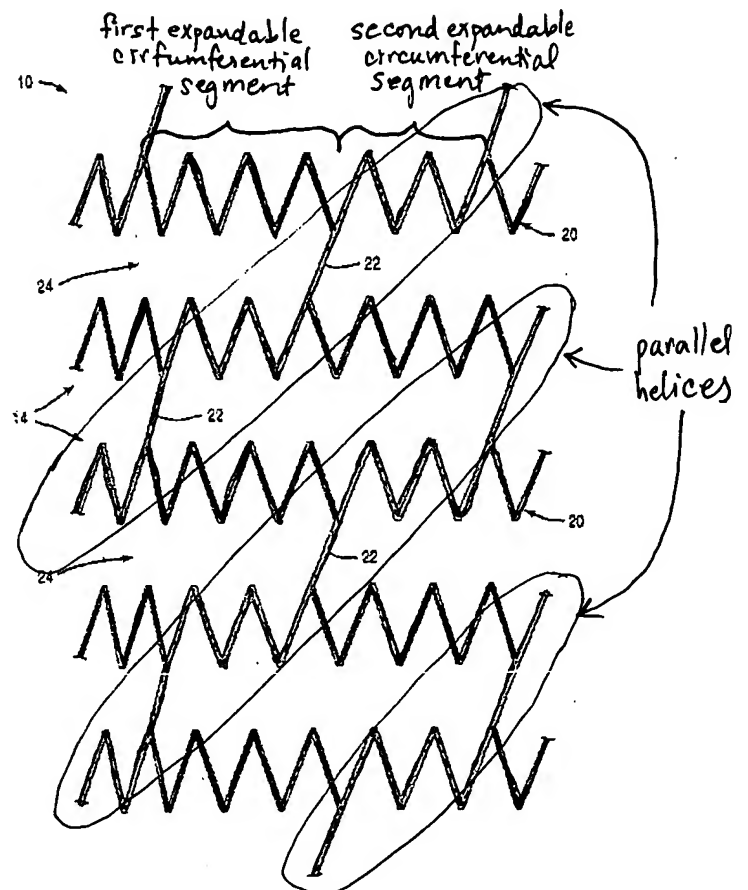


FIG. 2C

Claim 2, see Figures 2A and 2C for the circumferential segments being comprised of a plurality of segments joined together to form a repeating pattern.

Claim 3, see column 3, line 54 for an alternative embodiment wherein the repeating pattern comprises a square wave form having curved peaks and valleys (U-shaped).

Claims 4 and 5, see Figure 2A for a first and second endzone straddling the main body (12) of the stent (10) and further comprising a plurality of struts (22) connecting each endzone to the main body (12).

Claims 6 and 7, see Figure 2A for the diamond shaped endzones each comprised of two rings of a V-shaped pattern, wherein the rings in each endzone are joined together by a plurality of struts (the struts making up the V-shaped pattern).

Claims 8 and 9, see column 3, line 54 for an alternative embodiment wherein the rings are comprised of a plurality of alternating linear and curved segments (N-shaped pattern), and the slanted linear segments of the N-shaped pattern form an angle greater than zero degrees relative to the cylindrical axis of the cylindrical elements.

Claim 11, see column 8, lines 52-54 and 61-63 for the material of the stent (10) rendering at least a portion of the stent (10) radiopaque.

Claim 12, see Figure 2A for each of the endzones being attached to the main body (12) with a plurality of struts (22).

Claim 13, see columns 7-8, lines 64-33 for the stent (10) being manufactured from a contiguous piece of material.

Claim 14, see column 10, lines 11-13. In an embodiment with only two connectors (22) extending between adjacent cylindrical main body elements (14), there will be two helical segments in the main body (12) that are 180 degrees apart.

Claim 15, see Figure 2A for each endzone comprising a ring formed from a plurality of contiguous segments.

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Claim 16, see column 3, line 54 for an alternative embodiment wherein the contiguous segments comprise linear and curved segments that are joined together to form a repeating N-shaped pattern.

Claim 17, see column 3, line 54 for an alternative embodiment wherein the first expandable circumferential element comprises a plurality of linear and curved segments joined together to form a repeating N-shaped pattern that resembles generally a square wave form having curved peaks and valleys.

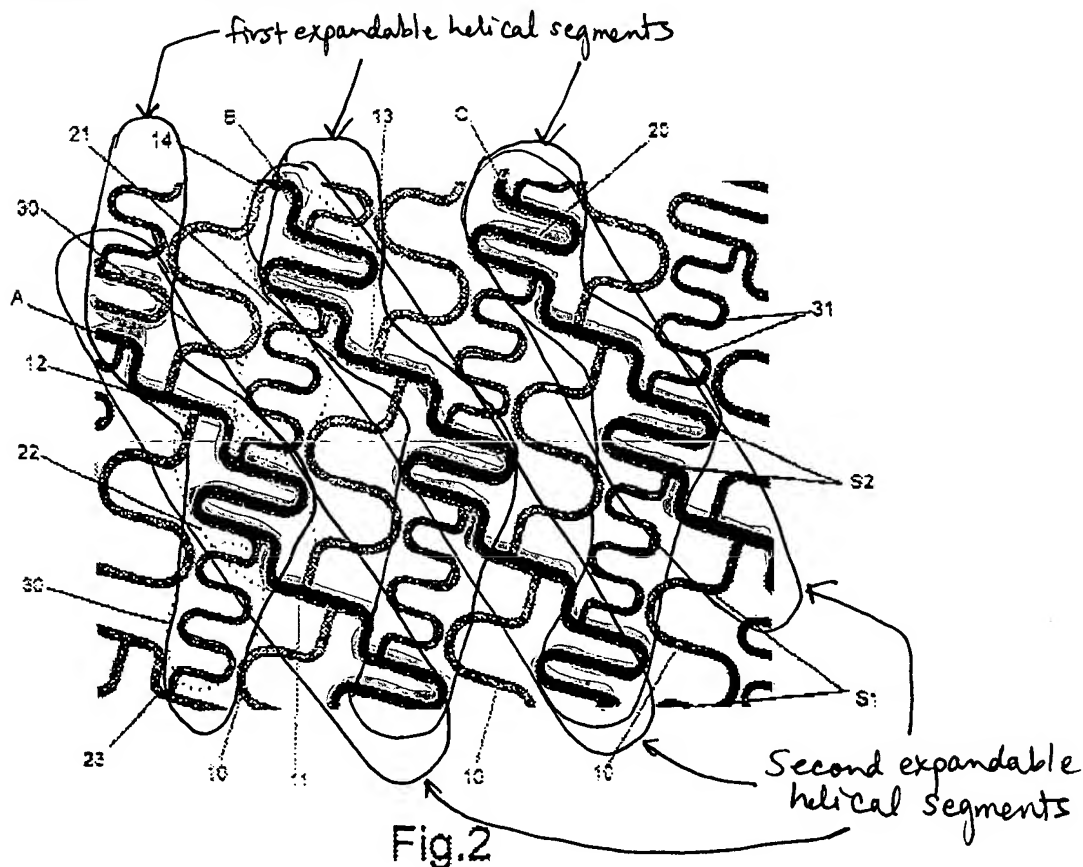
Claim 18, see column 3, line 54 for an alternative embodiment wherein the second expandable element comprises a plurality of linear and curved segments joined together and wherein the slanted linear segments of the N-shaped pattern form an angle relative to the cylindrical axis of the stent that is *approximately* equal to the helical angle of at least one of the helixes in the main body.

7. Claims 19, 20, 23-27, 29, 30 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Cottone et al. (USPN 6,432,132).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Cottone et al. discloses an expandable stent with all the elements of claims 19 and 29.

With respect to claim 19, see Figure 1 and Figure 2 below for a stent including a cylindrical axis and a cylindrical main body about the cylindrical axis. The main body includes a plurality of first expandable helical segments having a first pitch, and a plurality of second expandable helical segments having a second pitch that differs in value from the first pitch, wherein the first helical segments cross the second helical segments.



With respect to claim 29, see Figure 1 and Figure 2 below for a stent including a plurality of first expandable segments, a plurality of second expandable segments, and a plurality of adjacent cylindrical main body elements having collinear cylindrical axes and being formed by

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connecting first expandable segments with second expandable segments. A plurality of first helical segments having a pitch are formed by connecting first expandable segments from adjacent cylindrical elements with each other, and a plurality of second helical segments having a different pitch from the first helical segments are formed by connecting second expandable segments from adjacent cylindrical elements with each other.

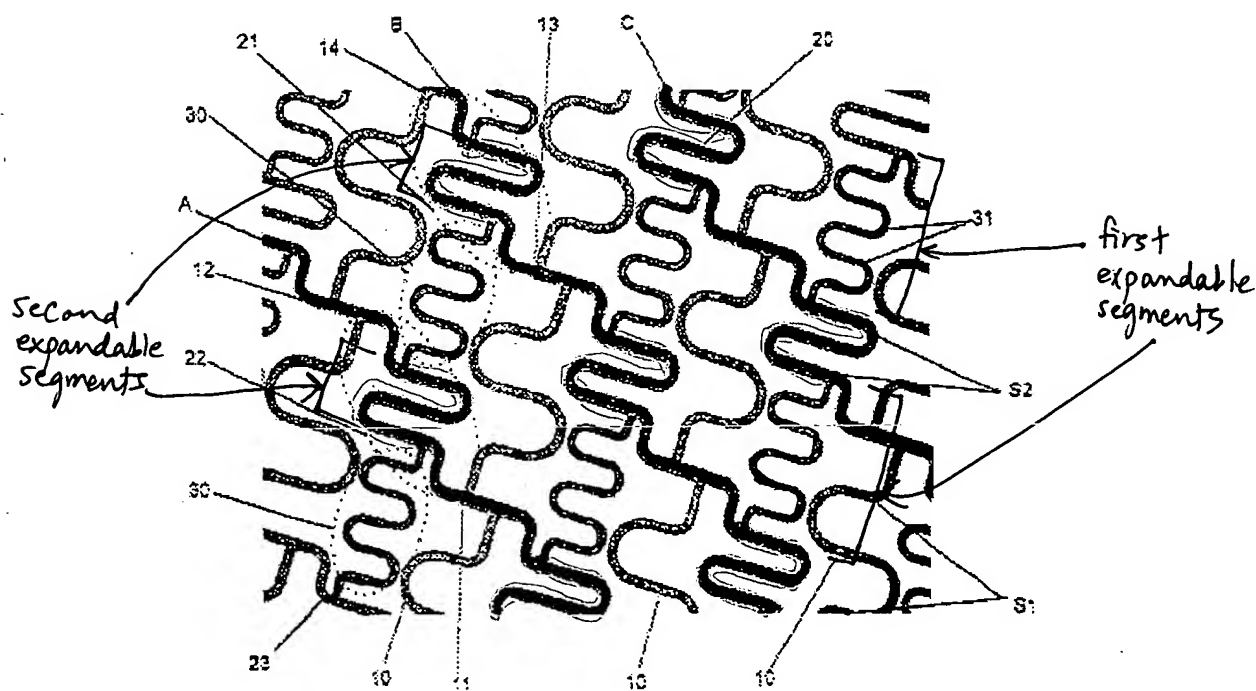


Fig. 2

Claim 20, see Figures 1 and 2 for the second pitch having a value that is approximately twice that of the first pitch.

Claim 23, see column 7, lines 48-62 for the first helical segments being comprised of a plurality of circumferential segments joined together to form a helix.

Claim 24, see Figure 2 for the circumferential segments being comprised of a plurality of linear and curved segments joined together.

Claim 25, see Figure 1 for the linear segments lying at an angle between 0-45 degrees with respect to the cylindrical axis of the stent.

Claim 26, see Figure 2 above for the second helical segments being comprised of a plurality of second circumferential elements joined together to form a second helix.

Claim 27, see column 5, line 40 for the material of the stent rendering the stent radiopaque.

Claim 30, see Figure 2 for the first and second expandable segments being joined together by a connecting segment (20).

Claim 33, see Figure 1 for at least one helical segment forming an angle of *approximately* 40 degrees relative to the cylindrical axis of the stent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 21, 22 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over Cottone et al. ('524) in view of Cottone, Jr. et al. (USPAP 2002/0116044, as cited in last office action).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

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102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Cottone et al. ('524) discloses an expandable stent with all the elements of claims 19 and 29, but silent to the additional limitations of a plurality of generally cylindrical shaped endzones having cylindrical axes that are collinear with the main body cylindrical axis, as required by claim 21, wherein the endzones have square outer edges, as required by claim 22, and first and second endzones straddling the main body, as required by claim 32. Cottone, Jr. et al. (USPAP) teaches an expandable stent with cylindrical endzones (81) having square outer edges that are collinear with the main body cylindrical axis and straddle the main body in order for the stent to have closed ends that are substantially perpendicular to the axis of the stent. See Figures 1 and 7 and paragraph [0037]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Cottone, Jr. et al. (USPAP) to modify the

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stent of Cottone et al. ('524) by including the endzones as required by claim 21, 22 and 32 in order for the stent to have closed ends that are substantially perpendicular to the axis of the stent.

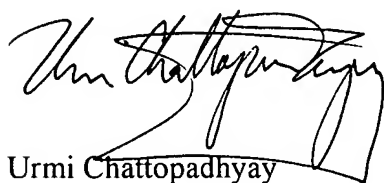
Allowable Subject Matter

10. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner